

Appl. No.: 10/796,307
Atty. Docket No.: CL1509ORD

REMARKS

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Status of the claims

Claims 1-24 are pending. Claims 1 and 21 have been amended by this amendment. Claim 5 has been canceled by this amendment without prejudice or disclaimer. No new matter has been added by this amendment. Support for amended claims 1 and 21 can be found in Table 2, Table 7, the Sequence Listing, and pages 119-123 of the specification.

This amendment adds, changes and/or deletes claims in the instant application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, are presented with an appropriate defined status identifiers. See 37 C.F.R. §1.121(c).

The Restriction Requirement and Applicants' election

In the Restriction Requirement, the Examiner requested Applicants elect one of the following inventions:

Group I, Claims 1-6, and 21-22, drawn to methods for identifying an individual who has an altered risk for developing myocardial infarction (MI) using a SNP.

Group II, Claims 7-9, and 13-20, drawn to nucleic acids.

Group III, Claim 10, drawn to polypeptides.

Group IV, Claims 11-12, drawn to antibodies.

Group V, Claim 23, drawn to methods for detecting a variant polypeptide.

Group VI, Claims 24, drawn to methods of identifying an agent.

The Examiner also issued a further restriction requirement to all groups having more than one nucleotide or amino acid sequence.

Applicants hereby provisionally elect, with traverse, to prosecute Group I, Claims 1-6, and 21-22, drawn to methods for identifying an altered risk for developing MI diseases by detecting the presence of various SNPs, in particular, the polymorphism of hCV25753038, also known as rs6685323, as represented by SEQ ID NO.: 33944. More information on this polymorphism can be found in Table 2, Table 6, the Sequence Listing, and in the Example section starting from page 119.

For reasons stated below, Applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement, including the additional restriction requirement of the selection of just one polymorphism sequence for examination.

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Under MPEP §803, for a restriction requirement to be proper, the Examiner has a serious burden to make a *prima facie* case that the following two criteria are met:

- 1). The inventions must be independent or distinct as claimed; **and**
- 2). There would be a serious burden on the examiner if restriction is not required.

Applicants respectfully submit that the Examiner has not met the burden. Applicants submit that the search and examination of claims as encompassed by the various groups is not unduly burdensome. For example, a search of the prior art to determine the novelty of the polypeptides of Group III would provide information regarding the novelty of the methods for detecting such polypeptides of Group V, and for identifying an agent of Group VI, which binds to the polypeptides.

With respect to the specific polymorphism sequence election requirement, Applicants wish to draw the Examiner's attention to MPEP §803.04, which addresses restriction requirement relating to nucleotide sequences.

The Examiner's attention is directed to MPEP §803.04. See also *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996). There, while recognizing that nucleotide sequences "are deemed to normally constitute independent and distinct inventions", the Director "has decided *sua sponte* to partially waive the requirements of 37 CFR §1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application" in the interest "to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office."

The MPEP further announces that it "has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." MPEP §803.04, Eighth Edition, Revision 3, August 2005.

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Therefore, Applicants hereby respectfully request that the following ten (10) nucleotide sequences in Group I be included in the examination. The ten sequences, together with their public identifiers, are shown in the table below.

More detailed information about these ten sequences can be found in Table 2, the Sequence Listing, and in the data tables as indicated below.

hCV	rs	SEQ ID NO	Data Table
hCV25753038	rs6685323	33944	6
hCV9596971	rs6119	21614	7
hCV7514870	rs1041981	36349	7
hCV22271851/hCV15954570	rs2236493	25917	8
hCV2603661	rs679779	21749	8
hCV25607108	rs10204137	29108	8
hCV25751017	none	27819	8
hCV25644901	none	10810	8
hCV440166	rs3795299	11670	8
hCV15853281	rs17479168	28735	6

In the event the Examiner maintains the Restriction Requirement, Applicants reserve the right to request rejoinder of any process claims limited in scope to allowable product claims in accordance with *In re Ochiai*, and further reserve the right to prosecute the subject matter of non-elected claims in subsequent divisional applications without prejudice.

The Examiner is invited to contact the undersigned via telephone if a phone interview would expedite the prosecution of the instant patent application.

Respectfully submitted,

By:


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